

**Nguyet Phan**

10/01/02 06:42 AM

To: NCIC HPV

CC:

Subject: HPV Challenge Program, AR-201 - Registration Number: 1100319

----- Forwarded by Nguyet Phan/DC/USEPA/US on 10/01/02 06:42 AM -----

**NATALIE\_RUTHERFORD@fmc.com on 09/29/2002 11:02:54 PM**



To: NCIC OPPT/DC/USEPA/US@EPA, Rtk Chem/DC/USEPA/US@EPA  
cc: Richard Hefter/DC/USEPA/US@EPA, John\_Becker@fmc.com, Amelia\_Jackson-Gheissari@fmc.com

Subject: HPV Challenge Program, AR-201 - Registration Number: 1100319

FMC Corporation actively supports the EPA HPV Challenge Program, AR-201. Attached is FMC's response to the EPA comments posted on July 31, 2002 regarding our December 28, 2001 submission to the RTK HPV Challenge Program of the test plan and robust summaries for the single chemical:

•Phenol, 2-[(2-methyl-2-propenyl) oxy]; Methallyloxyphenol -- CAS No. 4790-71-0

The attached files include FMC's Response to EPA comments, a Revised Test Plan and Revised Robust Summaries. Revisions made to the test plan and robust summaries appear in red.

Please contact me if you have comments or questions regarding FMC's submission.

Sincerely,

Natalie Rutherford  
Manager, Global Regulatory Affairs  
FMC Corporation  
1-213-299-6680



- MOP - Comments.doc



- MOP - Rev Test Plan.doc



- MOP - Rev Summaries.doc

## FMC Response to EPA Comments on the METHYLALLYLOXYPHENOL Test Plan

### **Chemistry (melting point, boiling point, vapor pressure, water solubility, and partition coefficient).**

#### EPA Comment

EPA agrees with the submitter's proposal to conduct partition coefficient and water solubility tests. Adequate existing data are available for the other endpoints.

#### FMC Response

No Response.

### **Environmental Fate (photodegradation, stability in water, biodegradation, and transport/distribution).**

#### EPA Comment

EPA agrees with the submitter's proposal to conduct hydrolysis and biodegradation tests. Adequate existing data are available for the other endpoints. However, the submitter needs to provide the in-put values for the fugacity calculation.

#### FMC Response

The robust summary has been revised to include all input values for the fugacity calculation. The only user input in the model is the structure of the molecule. All other input values are calculated by EPI-WIN. An explanation of the fugacity model used in EPI-WIN has also been added to the robust summary for reference.

### **Health Effects**

#### EPA Comment

The submitter proposes to conduct a developmental toxicity study (deferred until 2003). Adequate data are available for the acute and genetic toxicity endpoints. The submitter notes that neither repeated dose toxicity nor reproductive toxicity data are needed because MOP is a "closed system intermediate" as defined by EPA for the HPV Challenge Program.

#### *Reproductive and Repeat Dose Toxicity*

The Guidance for Testing Closed System Intermediates for the Challenge Program <http://www.epa.gov/chemrtk/guidocs.htm> allows for a reduced testing proposal provided certain criteria are met. The information required to judge a "closed system intermediate" claim must address the following:

- I. Site information.
  - A. Number of sites.
  - B. Basis for "closed process" conclusion at each site.
    - 1) Process description.
    - 2) Monitoring data showing no detection.

3) In the absence of monitoring data, the basis for believing that releases do not occur.

C. Data on "presence in distributed products."

II. Information on transport (mode, volume, controls, etc.)

III. A data search showing that the chemical is not present in other endproducts.

EPA believes that the submitter has adequately addressed the criteria described above. MOP is produced at a single site, is consumed in the in-process reaction to make another substance, and there are no off-site shipments. No data are available to indicate MOP is present in other products above trace levels.

#### FMC Response

FMC plans to conduct OECD Guideline 421 in 2003 to satisfy the Developmental Toxicity Study.

#### **Ecological Effects (fish, daphnid, and algal toxicity).**

##### EPA Comment

Adequate existing data are available for these endpoints. A study detail needs to be provided in a number of the robust summaries.

##### FMC Response

All of the Ecological studies were conducted under GLP. The solvent volume in all static tests was not greater than 0.5ml/l and the solvent volume in the flow through tests was not greater than 0.1ml/l. The exact amounts of solvent used in these studies will be determined and added to the robust summaries.

#### **FMC Response to EPA Comments on the METHYLALLYLOXYPHENOL Robust Summaries**

#### **Environmental Fate (photodegradation, stability in water, biodegradation, and transport/distribution).**

##### EPA Comment

*Transport/distribution.* The submitter needs to provide the in-put values for the fugacity calculation.

##### FMC Response

The robust summary has been revised to include all input values for the fugacity calculation. The only user input in the model is the structure of the molecule. All other input values are calculated by EPI-WIN. An explanation of the fugacity model used in EPI-WIN has also been added to the robust summary for reference.

#### **Ecological Effects (fish, daphnid, and algal toxicity).**

##### EPA Comment

The submitter needs to address the amount of solvent used in the studies.

#### FMC Response

All of the Ecological studies were conducted under GLP. The solvent volume in all static tests was not greater than 0.5ml/l and the solvent volume in the flow through tests was not greater than 0.1ml/l. The exact amounts of solvent used in these studies will be determined and added to the robust summaries.